Please type a plus sign (+) inside this box →

PTO/SB/08A (10-96
Approved for use through 10/31/99. OMB 0651-0031
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet | | of | 8

Complete if Known	
Application Number	08/765,324
Filing Date	December 24, 1996
First Named Inventor	Eugen Koren et al.
Group Art Unit	1818
Examiner Name	P. Duffy
Attorney Docket Number	OMRF 143 cip(2)

U.S. PATENT DOCUMENTS

Examiner's Initials*	Cite No.[1]	US Patent Document Number	Kind Code[2] (if known)	Name of Patentee or Applicant of Cited Document	Date of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
PAD		4,786,589		Pounds et al.	12/22/88	
PAD		4,376,110		David et al.	3/8/83	

FOREIGN PATENT DOCUMENTS

Examiner's Initials*	Cite No.[1]	Foreign Patent Document Office[3]	Number[4]	Kind Code[5] (if known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]
PAD			0 407 035 A2	Europe		01/09/91		
PAD			0 257 778 A2	Europe		03/02/88		
PAD			WO 86/05493	PCT		09/25/86		
PAD			WO 93/07165	PCT		04/15/93		
PAD			WO 93/18067	PCT		9/16/93		

Examiner's Signature	PATRICIA A. DUFFY	Date Considered	19 Jan 98

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] Unique citation designation number [2] See attached Kinds of U.S. Patent Documents. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6] Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you require to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Please type a plus sign (+) inside this box →

PTO/SB/08A (10-96
Approved for use through 10/31/99. OMB 0651-0031
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 2 of 8

Complete if Known	
Application Number	08/765,324
Filing Date	December 24, 1996
First Named Inventor	Eugen Koren et al.
Group Art Unit	1818
Examiner Name	P. Duffy
Attorney Docket Number	OMRF 143 CIP(2)

OTHER ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, cit and/or country where published	T[2]
PAD		Alaupovic, P., et al., "Characterization of Potentially Atherogenic Triglyceride-rich Lipoprotein Particles", *Klin Wochenschr*, 68:38-42 (1990).	
		Alaupovic, P., et al., "Distribution of Lipoprotein Families in Major Density Classes of Normal Human Plasma Lipoproteins", *Biochim. Biophys. Acta*, 260:689-707 (1972).	
		Alaupovic, P., et al., "Isolation and Characterization of an apoA-II-Containing Lipoprotein (LP-A-II:B Complex) from Plasma Very Low Density Lipoproteins of Patients with Tangier Disease and Type V Hyperlipoproteinemia", *J. Lipid Res.*, 32:9-19 (1991).	
		Alaupovic, P., "David Rubinstein Memorial Lecture: The Biochemical and Clinical Significance of the Interrelationship Between Very Low Density and High Density Lipoproteins", *Can. J. Biochem.*, 59:565-579 (1981).	
		Arntzenius, A.C., "Regression of Atherosclerosis - Benefit can be Expected from Low LDL-C and High HDL-C Levels", *Acta. Cardiol.*, 46:431-438 (1991).	
		Assmann, G., et al., "The Hypertriglyceridemias: Risk and Management", *Am. J. Cardiol.*, 68(3):1A-4A (1991).	
		Atmeh, R.F., et al., "Subpopulations of Apolipoprotein A-I in Human High-Density Lipoproteins, Their Metabolic Properties and Response to Drug Therapy", *Biochim. Biophys. Acta*, 751:175-188 (1983).	
		Avogardo, P., et al., "Are Apolipoproteins Better Discriminators than Lipids for Atherosclerosis?", *Lancet*, 1:901-903 (1979).	
		Barth, J.D., et al., "Progression and Regression of Atherosclerosis, What Roles for LDL-Cholesterol and HDL-Cholesterol: A Perspective", *Eur. Heart J.*, 12:952-957 (1991).	
		Blankenhorn, D.H., et al., "Prediction of Angiographic Change in Native Human Coronary Arteries and Aortocoronary Bypass Grafts", *Circulation*, 81(2):479-476 (1990).	
✓		Cardin, A.D., et al., "Degradation of Apolipoprotein B-100 of Human Plasma Low Density Lipoproteins by Tissue and Plasma Kallikreins", *J. Biol. Chem.*, 259(13):8522-8528 (1984).	

Examiner's Signature	PATRICIA A. DUFFY	Date Considered	19 Jan 98

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] Unique citation designation number [2] See attached Kinds of U.S. Patent Documents. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6] Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you require to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Please type a plus sign (+) inside this box →

PTO/SB/08A (10-96)
Approved for use through 10/31/99. OMB 0651-0031
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 3 of 8

Complete if Known	
Application Number	08/765,324
Filing Date	December 24, 1996
First Named Inventor	Eugen Koren et al.
Group Art Unit	1818
Examiner Name	P. Duffy
Attorney Docket Number	OMRF 143 CIP(2)

OTHER ART -- NON PATENT LITERATURE DOCUMENTS

Examiner's Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, cit and/or country where published	T[2]
PAD		Clackson, T. et al., *Nature*, 352: 624-628 (1991)	
		Curry, M.D., et al., "Determination of Apolipoprotein A and Its Constitutive A-I and A-II Polypeptides by Separate Electroimmunoassays", *Clin. Chem.*, 22(3):315-322 (1976).	
		Curry, M.D., et al., "Electroimmunoassay, Radioimmunoassay, and Radial Immunodiffusion Assay Evaluated for Quantification of Human Apolipoprotein B", *Clin. Chem.*, 24(2):280-286 (1978).	
		Curry, M.D., et al., "Determination of Human Apolipoprotein E by Electroimmunoassay", *Biochim. Biophys. Acta*, 439:413-425 (1976).	
		Curry, M.D., et al., "Quantitative Determination of Human Apolipoprotein C-III by Electroimmunoassay", *Biochim. Biophys. Acta*, 617:503-513 (1980).	
		Cwirla, S.E. et al., *Proc. Natl. Acad. Sci. USA*, 87: 6378-6382 (1990)	
		Friedewald, W.T., et al., "Estimation of the Concentration of Low-Density Lipoprotein Cholesterol in Plasma, Without Use of the Preparative Ultracentrifuge", *Clin. Chem.*, 18(6):499-502 (1972).	
		Fruchart, J.E., et al., "Apolipoprotein A-Containing Lipoprotein Particles: Physiological Role, Quantification, and Clinical Significance", *Clin. Chem.*, 38(6):793-797 (1992).	
		Fruchart et al., Clin. Chem., 28(1):59-62, (1982).	
		Galeano, N.F., et al., *J. Biol. Chem.*, "Apoprotein B Structure and Receptor Recognition of Triglyceride-rich Low Density Lipoprotein (LDL) is Modified in Small LDL but Not in Triglyceride-rich LDL of Normal Size", 269(1):511-519 (1994).	
✓		Galeano, N.F. et al., J. Biol. Chem., 269:511-519 (1994)	

Examiner's Signature	PATRICIA A DUFFY	Date Considered	19 Jan 98

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] Unique citation designation number [2] See attached Kinds of U.S. Patent Documents. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6] Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you require to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Please type a plus sign (+) inside this box →

PTO/SB/08A (10-96
Approved for use through 10/31/99. OMB 0651-0031
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 4 of 8

Complete if Known	
Application Number	08/765,324
Filing Date	December 24, 1996
First Named Inventor	Eugen Koren et al.
Group Art Unit	1818
Examiner Name	P. Duffy
Attorney Docket Number	OMRF 143 CIP(2)

OTHER ART -- NON PATENT LITERATURE DOCUMENTS

Examiner's Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, cit and/or country where published	T[2]
PAD		Glenner, G.G., "Formazans and Tetrazolium Salts", *In: H.J. Conn's Biological Stains*, The Williams and Wilkins Company, USA, 225-235 (1990).	
		Goding, "monoclonal Antibodies: Principles and Practice", Academic Press, Inc, New Yorkpp 56-97 (1983).	
		Gohlke, H., "Influence of the LDS-/HDL-Cholesterol Ratio on Progression and Regression of Atherosclerotic Lesions. A Review of Controlled Angiographic Intervention Trials", *Wien Klin. Wochenschr.*, 104(11):309-313 (1992).	
		Gordon, T., et al., "High Density Lipoprotein as a Protective Factor Against Coronary Heart Disease", *Am. J. Med.*, 62:707-714 (1977).	
		Harduin, P., et al., "Modulation of the Expression of Human LDL-Apo B-100 Epitopes by Lipids and Apolipoproteins", *Arterioscl. Thromb.*, 13(4):529-535 (1993).	
		Hollinger, P., et al., "'Diabodies': Small bivalent and Bispecific Antibody Fragments", *Proc. Natl. Acad. Sci. USA*, 90:6444-6448 (1993).	
		Hoogenboom, H.R., et al., "Multi-Subunit Proteins on the Surface of Filamentous Phage: Methodologies for Displaying Antibody (Fab) Heavy and Light Chains", *Nucl. Acids Res.*, 19(15):4133-4137 (1991).	
		Ito, W., et al., "Development of an Artificial Antibody System with Multiple Valency Using an Fv Fragment Fused to a Fragment of Protein A", *J. Biol. Chem.*, 268(27):20668-20675 (1993).	
		Kane, J.P., "Characterization of Apolipoprotein B-Containing Lipoproteins", *Method. Enzymol.*, 129:123-129 (1986).	
		Kashyap, M.L., et al., "Radioimmunoassay of Human Apolipoprotein CII - A Study in Normal and Hypertriglyceridemic Subjects", *J. Clin. Invest.*, 60:171-180 (1977).	
↓		Keidar, S., et al., "A High Carbohydrate-Fat Free Diet Alters the Proportion of Heparin-Bound VLDL in Plasma and the Expression of VLDL-ApoB-100 Epitopes", *Metabolism*, 39(3):281-288 (1990).	

Examiner's Signature	PATRICIA A. DUFFY	Date Considered	19 Jan 98

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] Unique citation designation number [2] See attached Kinds of U.S. Patent Documents. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6] Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you require to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Please type a plus sign (+) inside this box →

PTO/SB/08A (10-96
Approved for use through 10/31/99. OMB 0651-0031
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 5 of 8

Complete if Known	
Application Number	08/765,324
Filing Date	December 24, 1996
First Named Inventor	Eugen Koren et al.
Group Art Unit	1818
Examiner Name	P. Duffy
Attorney Docket Number	OMRF 143 CIP(2)

OTHER ART -- NON PATENT LITERATURE DOCUMENTS

Examiner's Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, cit and/or country where published	T[2]
PAD		Koren, E., et al., "Isolation and Characterization of Simple and Complex Lipoproteins Containing Apolipoprotein F from Human Plasma", *Biochemistry*, 21:5347-5351 (1982).	
		Koren, E., et al., "Apolipoprotein A-I and Apolipoprotein B Containing Lipoprotein Particles in Coronary Patients Treated with Extracorporal Low Density Lipoprotein Precipitation (HELP)", *Atherosclerosis*, 95:157-170 (1992).	
		Koren, E., et al., "Characterization of a Monoclonal Antibody that Binds Equally to All Apolipoprotein and Lipoprotein Forms of Human Plasma Apolipoprotein B. I. Specificity and Binding Studies", *Biochim. Biophys. Acta*, 876:91-100 (1986).	
		Koren, E., et al., "Characterization of a Monoclonal Antibody that Binds Equally to All Apolipoprotein and Lipoprotein Forms of Human Plasma Apolipoprotein B. II. Isolation of Apolipoprotein B-Containing Lipoproteins from Human Plasma", *Biochim. Biophys. Acta*, 876:101-107 (1986).	
		Koren, E., et al., "Use of 'Pan' Monoclonal Antibody for Quantification of Apolipoprotein A-II", *Arteriosclerosis*, 6:521a (1986).	
		Koren, E., et al., "Quantification of Two Different Types of Apolipoprotein A-I Containing Lipoprotein Particles in Plasma by Enzyme-Linked Differential-Antibody Immunosorbent Assay", *Clin. Chem.*, 33(1):38-43 (1987).	
		Krauss, R.M., "Relationship of Intermediate and Low-Density Lipoprotein Subspecies to Risk of Coronary Artery Disease", *Am. Heart J.*, 113(2):578-582 (1987).	
		Krodel, E., et al., "Technical Challenges in the Development of the CIBA Corning ACS:180 Benchtop Immunoassay Analyzer", *In: Bioluminescence and Chemiluminescence: Current Status*. John Wiley and Sons Inc., New York, 107-110 (1991).	
		Kuyl, J.M., et al., "Observed Relationship Between Ratios HDL-Cholesterol/Total Cholesterol and Apolipoprotein A1/Apolipoprotein B", *Clin. Biochem.*, 25:313-316 (1992).	
		Kwiterovich, P.O., Jr., et al., "Prevalence of Hyperapobetalipoproteinemia and Other Lipoprotein Phenotypes in Men (Aged ≤50 Years) and Women (≤60 Years) With Coronary Artery Diseases", *Am. J. Cardiol.*, 71:631-639 (1993).	
↓		Kwiterovich, P.O., Jr., et al., "Comparison of the Plasma Levels of Apolipoprotein B and A-1, and Other Risk Factors in Men and Women with Premature Coronary Artery Disease", *Am. J. Cardiol.*, 69:1015-1021 (1992).	

Examiner's Signature	PATRICIA A. DUFFY	Date Considered	19 Jan 98

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] Unique citation designation number [2] See attached Kinds of U.S. Patent Documents. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6] Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you require to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Please type a plus sign (+) inside this box →

PTO/SB/08A (10-96)
Approved for use through 10/31/99. OMB 0651-0031
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 6 of 8

Complete if Known	
Application Number	08/765,324
Filing Date	December 24, 1996
First Named Inventor	Eugen Koren et al.
Group Art Unit	1818
Examiner Name	P. Duffy
Attorney Docket Number	OMRF 143 CIP(2)

OTHER ART -- NON PATENT LITERATURE DOCUMENTS

Examiner's Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, cit and/or country where published	T[2]
PAD		La Belle, M., et al., "Increased Immunoreactivity of Apolipoprotein B Epitopes During Prolonged Storage of Low Density Lipoproteins", *Clin. Chim. Acta*, 191: 153-160 (1990).	
		Lee, D.M., et al., "Properties of Apolipoprotein B in Urea and in Aqueous Buffers - The Use of Glutathione and Nitrogen in its Solubilization", *Biochim. Biophys. Acta*, 666:133-146 (1981).	
		Lopes-Virella, M.F., et al., "Cholesterol Determination in High-Density Lipoproteins Separated by Three Different Methods", *Clin. Chem.*, 23:(5):882-884 (1977).	
		Lowman et al., Biochemistry, 30:10832-10838.	
		Maciejko, J.J., et al., "Apolipoprotein A-I as a Marker of Angiographically Assessed Coronary-Artery Disease", *N. Engl. J. Med.*, 309(7):385-389 (1983).	
		Marcel et al., J. Lipid Res., 28(7): 768-77 (1987).	
		McGill, D.A., et al., "Relationship of Blood Cholesterol and Apoprotein B Levels to Angiographically Defined Coronary Artery Disease in Young Males", *Coron. Artery Dis.*, 4(3):261-270 (1993).	
		Mézes. P., "Construction and Biodistribution Studies of Multivalent Single-Chain Antibodies", *Construction and Biodistribution Studies of Multivalent Single-Chain Antibodies, The Fourth Annual IBC International Conference on Antibody Engineering*, December 1993, Coronado, CA.	
		Miller, N.E., et al., "High-Density Lipoprotein and Coronary Heart-Disease: A Prospective Case-Control Study", *Lancet*, 1:965-968 (1977).	
		Miller, G.J., et al., "Plasma-High-Density-Lipoprotein Concentration and Development of Ischaemic Heart-Disease", *Lancet*, 1:16-19 (1975).	
↓		Milne, R., et al., "The Use of Monoclonal Antibodies to Localize the Low Density Lipoprotein Receptor-Binding Domain of Apolipoprotein B", *J. Biol. Chem.*, 264(33):19754-19760 (1989).	

Examiner's Signature	PATRICIA A. DUFFY	Date Considered	19 Jan 98

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] Unique citation designation number [2] See attached Kinds of U.S. Patent Documents. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6] Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you require to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Please type a plus sign (+) inside this box →

PTO/SB/08A (10-96)
Approved for use through 10/31/99. OMB 0651-0031
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 7 of 8

Complete if Known	
Application Number	08/765,324
Filing Date	December 24, 1996
First Named Inventor	Eugen Koren et al.
Group Art Unit	1818
Examiner Name	P. Duffy
Attorney Docket Number	OMRF 143 CIP(2)

OTHER ART -- NON PATENT LITERATURE DOCUMENTS

Examiner's Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, cit and/or country where published	T[2]
PAD		Mulder, K., et al., "An Evaluation of Three Commercial Methods for the Determination of LDL-Cholesterol", *Clin. Chim. Acta*, 143:29-35 (1984).	
		Olofsson, S-O, et al., "Isolation and Partial Characterization of a Polypeptide Belonging to Apolipoprotein B from Low-Density Lipoproteins of Human Plasma", *Biochemistry*, 19:1059-1064 (1980).	
		Ortolá, J., et al., "Biological Variation Data Applied to the Selection of Serum Lipid Ratios used as Risk Markers of Coronary heart Disease", *Clin. Chem.*, 38(1):56-59 (1992).	
		Osborne, J.D., et al., "The Plasma Lipoproteins", *Adv. Prot. Chem.*, 31:253-337 (1977).	
		Parham, P. "Handbook of Experimental Immunology, Vol. 1: Immunochemistry," Weir, D.M., Editor, Blackwell Scientific Publicatuons, Oxford (1986).	
		Parmley, S.F., et al., "Filamentous Fusion Phage Cloning Vectors for the Study of Epitopes and Design of Vaccines", *Adv. Exp. Med. Biol.*, 251:215-218 (1989).	
		Puchois, P., et al., "Apolipoprotein A-I Containing Lipoproteins in Coronary Artery Disease", *Atherosclerosis*, 68:35-40 (1987).	
		Savage, M.D., et al., "Avidin-Biotin Chemistry: A Handbook," Pierce Chemical Company, Rockford, IL (1992).	
		Smith, L.C., et al., "The Plasma Lipoproteins: Structure and Metabolism", *Ann. Rev. Biochem.*, 47:751-777 (1978).	
		Sniderman, A., et al., "Association of Coronary Atherosclerosis with Hyper*apo*betalipoproteinemia [Increased Protein but Normal Cholesterol Levels in Human Plasma Low Density (β) Lipoproteins], *Proc. Natl. Acad. Sci. USA*, 77(1):604-608 (1980).	
		Socorro, L., et al., "Preparation and Properties of Soluble, Immunoreactive apoLDL", *G.J. Lipid Res.*, 20:631-638 (1979).	

Examiner's Signature	PATRICIA A. DUFFY	Date Considered	19 Jan 98

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] Unique citation designation number [2] See attached Kinds of U.S. Patent Documents. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6] Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you require to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Please type a plus sign (+) inside this box →

PTO/SB/08A (10-96
Approved for use through 10/31/99. OMB 0651-0031
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 8 of 8

Complete if Known	
Application Number	08/765,324
Filing Date	December 24, 1996
First Named Inventor	Eugen Koren et al.
Group Art Unit	1818
Examiner Name	P. Duffy
Attorney Docket Number	OMRF 143 CIP(2)

OTHER ART -- NON PATENT LITERATURE DOCUMENTS

Examiner's Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, cit and/or country where published	T[2]
PAD		Stein, E.A., et al., "Lipids, Lipoproteins, and Apolipoprotein", *In Tietz Textbook of Clinical Chemistry*, W.B. Saunders, Philadelphia, 1002-1093 (1994).	
		Tornvall, P., et al., "Relation of Plasma Levels and Composition of Apolipoprotein B-Containing Lipoproteins to Angiographically Defined Coronary Artery Disease in Young Patients With Myocardial Infarction", *Circulation*, 88:2180-2189 (1993).	
		Warnick, G.R., et al., "Dextran Sulfate-Mg^{2+} Precipitation Procedure for Quantitation of High-Density-Lipoprotein Cholesterol", *Clin. Chem.*, 28(6):1379-1388 (1982).	
		Weeks, I., et al., "Two-Site Immunochemiluminometric Assay for Human α_1-Fetoprotein", *Clin. Chem.*, 29(8): 1480-1483 (1983).	
		Wollenweber, J., et al., "Comparative Serum Lipoprotein Analysis by Polyacrylamide Disc Gel and Agarose Gel Electrophoresis", *Clin Chim. Acta*, 29:411-420 (1970).	
		Wood, P., "Heterogeneous Fluoroimmunoassay", *Principles and Practice of Immunoassay*, Stockton Press, New York, 365-392 (1991).	
		"Report of the Working Group on Atherosclerosis of the National Heart and Lung and Blood Institute", 2 (Washington, D.C.: Government Printing Office, 1981) DHEW Publication No. (NIH) 82-2035).	
		"The Lipid Research Clinics Coronary Primary Prevention Trial Results: II, *JAMA*, 251:365-374 (1984).	
		"Report of the Expert Panel on Blood Cholesterol Levels in Children and Adolescents", *Pediatrics*, 89:525-584 (1992).	
		"Report of the National Cholesterol Education Program Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults," Arch. Intern. Med. 148:36-69 (1988).	

Examiner's Signature	PATRICIA A. DUFFY	Date Considered	19 Jan 98.

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] Unique citation designation number [2] See attached Kinds of U.S. Patent Documents. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6] Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you require to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.